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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/806,899

03/23/2004

Steven Petrou

1386/19

2461

25297

7590

08/28/2006

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EXAMINER

KAPUSHOC, STEPHEN THOMAS

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/806,899	PETROU ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Stephen Kapushoc	1634	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date: ____   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: ____   | 6) <input type="checkbox"/> Other: ____                                     |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 7, 8, 11-17, 20, and 21, drawn to nucleic acid based methods for the diagnosis of SMEI by detecting alteration in the SCN1A gene, classified in class 435, subclass 6.
  - II. Claims 18 and 19, drawn to amino acid based methods for the diagnosis of SMEI by detecting alteration in the SCN1A protein, classified in class 435, subclass 7.1.
  - III. Claim 22, drawn to a method of determining a treatment for a SMEI patient, classifiable in class 435, subclass 91.2.
  - IV. Claim 23, drawn to a method of determining the likelihood of adverse results from treatments of a SMEI patient, classifiable in class 435, subclass 91.2.

### **Requirement for further Restriction applicable to all groups:**

If applicant elects group I, II, III, or IV, applicant shall further select a single particular alteration from the alterations identified in Table 3. This is not an election of species. Claims requiring an SCN1A alteration from Table 3 will only be examined insofar as they require the selected alteration.

2. Claims 1-6, 9 and 10 link(s) inventions I and II. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s),

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claims 1-6, 9, and 10. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions of nucleic acid analysis (group I) and protein analysis (group II) require different reagents for the analysis of different biological molecules and provide different information (i.e. detection of a gene mutation versus detection of a variable polypeptide).
4. Inventions I and II are unrelated to inventions III and IV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

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different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, whereas the inventions of group I and II require the diagnosis of SMEI (e.g. associating an alteration in the SCN1A gene with SMEI), the inventions of groups III and IV require the different association of alterations in the SCN1A gene with treatments for SMEI (group III) or with the likelihood of adverse results from a treatment of SMEI.

5. Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case the inventions of groups III and IV require the different association of alterations in the SCN1A gene with treatments for SMEI (group III) or with the likelihood of adverse results from a treatment of SMEI.

6. Regarding the requirement for further Restriction, the different SCN1A nucleic acid and amino acid sequences resulting from the alterations identified in Table 3 are different because they are different biological molecules composed of unique nucleic acid and amino acid sequences that are not common to one another. A reference against one particular alteration of the SCN1A gene would not necessarily be considered a reference against any other different particular alteration of the SCN1A gene.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification

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and recognized divergent subject matter and because inventions I-IV require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is 571-272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen Kapushoc  
Art Unit 1634

*Jehanne Sitton*  
**JEHANNE SITTON**  
**PRIMARY EXAMINER**  
8/10/06